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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,528	03/17/2004	Lajos Hegedus	01662/53303	3513
26646	7590	10/04/2007	EXAMINER	
KENYON & KENYON LLP			WEGERT, SANDRA L	
ONE BROADWAY			ART UNIT	
NEW YORK, NY 10004			PAPER NUMBER	
			1647	
			NOTIFICATION DATE	DELIVERY MODE
			10/04/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@kenyon.com

<b>Office Action Summary</b>	Application No. 10/802,528	Applicant(s) HEGEDUS ET AL.	
	Examiner Sandra Wegert	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-66 is/are pending in the application.
- 4a) Of the above claim(s) 52,53 and 61-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-51 and 54-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/17/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The Amendment and Election, sent 12 July 2007, and the Information Disclosure Statement, submitted 17 March 2004 have been entered into the record. Applicants Cancelled claims 1-41 and added new claims 42-66.

Applicants elected Invention I (Claims 42-60), as well as an adriamicine analog and serum albumin. Applicants also discussed and defined the subgenera disclosed in Claims 46 and 58. Claims 52, 53 and 61-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Claims 42-51 and 54-60 are under consideration in the instant application.

### Claim Rejections/Objections

#### **Claim Rejections: Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 42-51 and 54-60 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of US Patent 6,743,826 (Hegedus, 2004). Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims an almost identical invention to that of the patent.

The claims of the instant application and US Patent 6,743,826 are not patentably distinct from each other for the following reasons:

Instant claims 42-51 and 54-60 are directed to a pharmaceutical composition comprising a composition having a high solubility ( $1 \times 10^{-4}$  M) and a high binding affinity to plasma proteins, such that a compound bound to the composition will be protein-bound and in spontaneous equilibrium with the plasma protein. Dependent claims specify the compounds that are bound (most of which are pharmaceutical agents) as well as the plasma proteins comprising the composition. Claims 1-41 of Patent 6,743,826 are drawn to the same composition as the instant application, with the same specified variations, and often using the same language in the claims, including the exact same solubility requirements and the same percentage of bound compound.

The specifications and drawings of each application or Patent are identical. Each specification discloses methods of making the compositions using several common

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pharmaceutical agents bound with albumin and gamma-globulin. Both specifications tested the binding affinities of the prepared compositions, used HPLC to confirm their chemical identities, and prepared lyophilized samples of the compositions suitable for clinical administration.

Since the compositions claimed in the instant application overlap in scope with those in the Patent or are, in many claims, *identical*, a Double-Patenting rejection is appropriate.

Conclusion: Claims 42-51 and 54-60 are not allowable for the reasons outlined above.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call  
800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW

24 September 2007

*Eileen B. O'Hara*  
EILEEN B. O'HARA  
PRIMARY EXAMINER